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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,424	05/10/2005	Kaoru Miyamoto	47232.5003/00US	4728

25297 7590 04/02/2009
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EXAMINER

DUNSTON, JENNIFER ANN

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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04/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,424	Applicant(s) MIYAMOTO ET AL.	
	Examiner JENNIFER DUNSTON	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7,8,12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 7,8 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Appendices I-III</u> . |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/2008 has been entered.

Receipt is acknowledged of an amendment, filed 11/13/2008, in which claims 2 and 6 were canceled, claim 1 was amended, and claim 13 was newly added. Claims 1, 7, 8, 12 and 13 are pending.

Any objection or rejection of record in the previous office actions not addressed herein is withdrawn.

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 8/2/2007 is acknowledged.

Claims 7, 8 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/2/2007.

Claims 1 and 13 are under consideration.

Response to Amendment – Declaration of Kazuya Yamada

The declaration under 37 CFR 1.132 filed 3/17/2008 is sufficient to overcome the rejection of claim 1 based upon insufficiency of disclosure under 35 U.S.C. 112, first paragraph as set forth in the last Office action.

The declaration provides evidence that the sequence of SEQ ID NO: 1 can repress transcription from the rat PKM and HKII promoters in cells co-transfected with NF-Y protein.

This evidence has been reconsidered in light of the amendments to the claims in the reply filed 11/13/2008 and the evidence on the record as a whole. Furthermore, Yamada et al (Frontiers in Bioscience, Vol. 14, pages 3724-3732, January 2009) provide evidence that the expression of ZHX3 is decreased in hepatoma cells of rat, and evidence that ZHX3 is capable of repressing the transcription of type II hexokinase and pyruvate kinase M genes in rat hepatoma cells.

Response to Arguments - 35 USC § 112

The rejection of claims 2 and 6 under 35 U.S.C. 112, first paragraph (enablement), is moot in view of Applicant's cancellation of the claims in the reply filed 11/13/2008.

Applicant's arguments, see pages 5-6, filed 11/13/2008, with respect to the rejection of claim 1 under 35 U.S.C. 112, first paragraph (enablement), have been fully considered and are persuasive. The previous rejection of claim 1 has been withdrawn.

The rejection of claims 2 and 6 under 35 U.S.C. 112, first paragraph (written description), is moot in view of Applicant's cancellation of the claims in the reply filed 11/13/2008.

Applicant's arguments, see pages 6-8, filed 11/13/2008, with respect to the rejection of claim 1 under 35 U.S.C. 112, first paragraph (written description), have been fully considered and are persuasive. The previous rejection of claim 1 has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ishikawa et al (DNA Research, Vol. 4, No. 5, pages 307-313, 1997; see the entire reference), as evidenced by GenBank Accession No. BAA23691.2 (GI: 20521029, May 2002; see the entire reference). This is a new rejection.

Ishikawa et al teach a protein of 459 amino acids encoded by cDNA clone KIAA0395 (e.g., Table 1).

GenBank Accession No. BAA23691 is cited only to show the amino acid sequence of the KIAA0395 protein taught by Ishikawa et al. The sequence of KIAA0395 is 100% identical to amino acids 242-502 of instant SEQ ID NO: 1 and is more than 85% identical to SEQ ID NO: 1 (878/956 amino acids or 92% identical to SEQ ID NO: 1; see the attached alignment in Appendix I). The high percent identity (99% identity to amino acids 78-956 of SEQ ID NO: 1) indicates that the KIAA0395 protein would have the same function as instant SEQ ID NO: 1, such as the repression of type II hexokinase and pyruvate kinase M gene expression.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tang et al (WO 01/57190 A2, cited in a prior action; see the entire reference) in view of GenBank Accession No. BAA23691.2 (GI: 20521029, May 2002; see the entire reference). This is a new rejection.

Tang et al teach that isolated polypeptides are separated from their natural source and contain, if anything, only a solvent, buffer, ion, or other component present in solution (e.g., page 11, lines 19-24). Tang et al teach an isolated polypeptide of SEQ ID NO: 1479 (e.g., page 28, lines 9-11). Further, Tang et al teach that the sequence of disclosed polypeptides may be modified by substitution of a selected amino acid residue in the coding sequence (e.g., page 31,

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lines 1-9). Moreover, Tang et al teach that methods of determining the identity and/or similarity of two polypeptides are known in the art (e.g., page 33, lines 1-15). Tang et al teach that guidance in determining which amino acid residues may be replaced, added or deleted without abolishing activities of interest may be found by comparing the sequence of the particular polypeptide with that of homologous peptides and minimizing the number of amino acid sequence changes made in regions of high homology or by replacing amino acids with a consensus sequence (e.g., page 10, lines 9-15).

The amino acid sequence of SEQ ID NO: 1479 is 956 amino acids in length and 99.9% identical to the amino acid sequence of SEQ ID NO: 1 (see the attached alignment in Appendix II). The only difference between SEQ ID NO: 1479 of Tang et al and instant SEQ ID NO: 1 is that it contains an asparagine residue at position 310, rather than a serine residue.

Tang et al do not teach a composition comprising a protein consisting of SEQ ID NO: 1, because position 310 is an asparagine residue.

GenBank Accession No. BAA23691.2 teaches the amino acid sequence of the KIAA0395.

It would have been within the skill of the art at the time the invention was made for the ordinary artisan to align the sequence of Tang et al with the sequence of GenBank Accession No. BAA23691.2. Sequence alignment is taught by Tang et al (e.g., page 31, lines 1-9). An alignment of the sequence of Tang et al and GenBank Accession No. BAA23691.2 is provided in Appendix III. Tang et al teach that it is within the skill of the art to make single amino acid substitutions based upon a sequence comparison with a homologous peptide. Because GenBank Accession No. BAA23691.2 teaches a homologous peptide with a serine at position 310 of the

amino acid sequence of SEQ ID NO: 1479 of Tang et al, it would have been within the skill of the art at the time the invention was made to replace the asparagine at position 310 with a serine in order to achieve the predictable result of providing a functional protein by substituting one naturally occurring amino acid for another.

Response to Arguments - 35 USC § 102

The rejection of claim 6 under 35 U.S.C. 102(b) as being anticipated by Tang et al is moot in view of Applicant's cancellation of the claim in the reply filed 11/13/2008.

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Tang et al has been withdrawn in view of Applicant's amendment to the claim in the reply filed 11/13/2008. Tang et al do not teach a protein that comprises amino acids 242-502 of SEQ ID NO: 1.

The rejection of claim 2 under 35 U.S.C. 102(e) as being anticipated by Isogai et al is moot in view of Applicant's cancellation of the claim in the reply filed 11/13/2008.

The rejection of claim 1 under 35 U.S.C. 102(e) as being anticipated by Isogai et al has been withdrawn in view of Applicant's amendment to the claim in the reply filed 11/13/2008. Isogai et al do not teach a protein that comprises amino acids 242-502 of SEQ ID NO: 1.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

/JD/

/Celine X Qian /
Primary Examiner, Art Unit 1636